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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,929	09/25/2003	Brian B. Lentrichia	2024738-2247387008 (11.02	8293

38732 7590 10/24/2005

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,929	LENTRICHIA ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *4-13 and 19-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV (Claims 14-18) in the reply filed on 9/8/2005 is acknowledged. The traversal is on the ground(s) that the claims of Group I (claims 1-3 should be examined since the examination of these two groups is not burdensome. Additionally, Applicants assert that all claims should be examined despite the fact that the inventions are patentably distinct. In view of the election Office accepts that examination of Groups IV and I would not be burdensome and herewith rejoined the groups. However, as for rejoinder of all groups, Applicants' argument is not found persuasive because classification of the subject matter is a prima facie showing of burden, which is not overcome by applicant's assertion to the contrary. Only, claims **1-3, and 14-18** are considered.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-13, and 19-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/8/2005.

Applicants are reminded to cancel the non-elected claims.

Claim Rejections - 35 USC § 112

Claims 1-3, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, and 14 are vague and indefinite for recitation of "examining said collected material", what does this mean? There are no steps presented in the claims that define what such examination or analysis of biological sample entail. Claims are very confusing; these method claims do not set forth any steps. The claims require passing a medium across a filter, how much sample is supposes to be filtered? The claims have been interpreted in light of specification, and since the specification lacks proper teaching the claims are indefinite. Moreover, regarding claim 14, it is not clear what virus type is being "analyzed." Simple filtration does not lend itself to detection of anything. In addition, the type of cells, that are infected, should be identified. This affects the dependent claims.

Claims 1, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the required steps to analyze and examine are missing. This affects the dependent claims.

Claim Rejections - 35 USC § 112

Claims 1-3, and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure is rather deficient in providing adequate teaching. The entire teaching is directed to simple filtration of cells that are supposedly infected with virus. This, however, does not add anything to detection or analysis of how to detect or analyze the cells. How does utilization of cell filtration relate to detection or analysis of infected virus? The claims are directed to method of analyzing biological sample to detect virus, but the teaching is directed to isolation of cells on filters. There is a vast difference between the two. Method of isolating cells on filter is not the same as detecting a particular virus or virus in general. Applicants speak of shortcomings of state of the art, but frankly none of shortcomings have been addressed. Nor Applicants have solved any of the shortcomings. Applicants cannot expect others to enable their claimed invention. First, the Office absent clear teaching assumes that the colleted samples are small. Moreover the claims are directed to passing a medium-containing sample across a filter, but there is nothing in the specification that teaches how much sample is required. How much cells are needed to get efficacy with these methods? Is it a required step to grow the cells after isolating some from a patient? Additionally, it is not clear how collection of samples on filter lends support for a method of analysis and examination? Still further, if there are no steps for a specific virus, how does one know what to look for? The field of virus detection is

unpredictable, as Applicants own disclosure is tantamount to the unpredictability of the field, and in an unpredictable field the disclosure must provide teaching so one of ordinary skill in the art can practice the invention absent undue experimentation. The current disclosure does not provide anything except a broad recitation of filtration of cells with broad range of filter pore size. This is not adequate teaching for detection of virus in general or papillomavirus in particular, see Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. In the instant case the specification does not teach or provide any guidance for a general detection of cells infected by a virus, or human papillomavirus. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 14-18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ferguson Gary (US Patent No. 6,905,594 B2).

The above cited patent clearly anticipates the broad limitations of the claims 1, and 14. Ferguson taught a method of capturing materials suspended in a liquid utilizing a filter apparatus (see the abstract and all the claims). Additionally, the cited patent taught suspended materials can be viruses (see column 1, lines 18-28). Moreover, Ferguson taught the captured material can be analyzed such as visualization (see column 1, lines 29-32, and column 5, lines 1-5, column 8, lines 58-62).

As for claims 2-3, and 15-18, the cited patent taught pore filter size may be selected wherein the waste would go through, but the desired material would remain (see Column 7, lines 21-25). Ferguson did not specify the range of filter pore size or cell types. These differences, however, are deemed to be a design choice unless the proof of criticality is proven. The differences are within the purview of one ordinary skill in the art. Hence, the invention as a whole is prima facie obvious absent any unexpected results.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Radcliffe et al (US patent no. 5,942,700).

Radcliffe et al taught a method of collecting samples including biological samples through a filter wherein the particles can be further analyzed (see the claims, the abstract, and column 4, lines 55-57). The recitation of biological sample broadly incorporates virus, and papillomavirus. Additionally, they taught the filter size (see column 2, lines 44-50).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

10/21/2005